MAY 22 2014

510(k) Summary K132681
(As required by 21 CFR 807.92(a))

Summary of Safety and Effectiveness for the Sol-Guard Insulin and Tuberculin Safety Syringe

Date Prepared: August 26, 2013

A. Submitter Information

Sol-Millennium Medical, Inc.
5415 Sugarloaf Parkway
Suite 2203
Lawrenceville, GA 30043
Phone Number: 949-433-3058

Trade Name: Sol-Guard Insulin and Tuberculin Safety Syringes

B. Device Information

Trade/Proprietary Name:	Sol-Guard Insulin and Tuberculin Safety Syringes
Common name of device:	Piston syringe with safety feature
Classification Name:	Piston syringe
Product Code:	80 MEG
Regulatory Class:	II
Classification Number:	880.5860
Reason for 510(k):	New device

C. Predicate Device: Kendall Monoject Magellan Insulin and TB Safety Syringe

Predicate 510(k) #:	K061492
Predicate product code:	MEG

D. Device Description

The Sol-Guard Safety Syringe is a sterile, single use, standard hypodermic syringe with an attached Safety Shield to cover the needle. The Sol-Guard Safety Syringe will be labeled as either an Insulin Safety Syringe for U-100 insulin or as a Tuberculin Safety Syringe. The Safety Shield is extended by the user's finger or thumb. To lock the Safety Shield in place, the user turns the Safety Shield either right or left until it locks in place. Once the Safety Shield is locked in place, the Safety Shield can't be pulled back exposing the needle.

The Safety Shield on the Sol-Guard Safety Syringe covers the needle point after use. In the activated position, the Safety Shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.

The Sol-Guard Safety Syringe are sterilized by Ethylene Oxide Gas and supplied sterile in blister pack. One hundred blister packs are packaged in a chipboard box. Each Blister pack and chipboard box is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

E. Statement of Indications for Use

For Insulin Use

The Sol-Guard Insulin Safety Syringe is intended for the delivery of U-100 insulin.

The Sol-Guard Insulin Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.

For TB Use

The Sol-Guard Tuberculin (TB) Safety Syringe is intended for the delivery of Tuberculin.

The Sol-Guard TB Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Sol-Guard Insulin and TB Safety Syringe and the Kendall Monoject Insulin and TB Safety Syringes. The following comparison chart shows that the subject device and the predicate device are substantially equivalent:

Feature	Sol-Guard Insulin and TB Safety Syringes	Kendall Monoject Insulin and TB Safety Syringe
Syringe type	Piston syringe with Safety Shield	Piston syringe with Safety Shield
Intended Use	**For Insulin Use** The Sol-Guard Insulin Safety Syringe is intended for the delivery of U-100 Insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle sticks. **For TB Use** The Sol-Guard Insulin Safety Syringe is intended for the delivery of Tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle sticks.	**For Insulin Use** The device is intended for the delivery of U-100 Insulin. The needle stick prevention feature of the device, once activated, guards against accidental needle sticks. **For TB Use** The device is intended for the delivery of Tuberculin. The needle stick prevention feature of the device, once activated, guards against accidental needle sticks.
Principal of operation	The Sol-Guard Safety Syringe is a standard syringe with a shield. The shield can be extended to cover the needle for transport. In addition, once the injection is given, the shield is extended and rotated left or right and locked in place for disposal. The shield is designed to reduce needle stick injuries.	The Kendall Monject Safety Syringe is a standard syringe with a shield. The shield can be extended to cover the needle for transport. In addition, once the injection is given, the shield is extended and rotated left or right and locked in place for disposal. The shield is designed to reduce needle stick injuries.
Specific drug use	Insulin and Tuberculin	Insulin and Tuberculin
Needle		
Needle Length	1/2" – 1"	5/16"-5/8"
Needle Gauge	25 – 29	25 – 30
Nozzle type	Needle Hub	Needle Hub
Tip Configuration	15 degree regular point	15 degree regular point
Hub/needle bond strength	ISO 8537(Insulin) & ISO 7886 (TB)	ISO 8537(Insulin) & ISO 7886 (TB)
Barrel		
Barrel marking specs	ISO 8537(Insulin) & ISO 7886 (TB)	ISO 8537(Insulin) & ISO 7886 (TB)
Graduations legibility	ISO 8537(Insulin) & ISO 7886 (TB)	ISO 8537(Insulin) & ISO 7886 (TB)
Barrel transparency	Clear	Clear
Lubricant composition	Silicone Oil	Silicone Oil
Lubricant amount cm2	ISO 8537(Insulin) & ISO 7886 (TB)	ISO 8537(Insulin) & ISO 7886 (TB)
Syringe requirements		
Delivery accuracy	ISO 8537(Insulin) & ISO 7886 (TB)	ISO 8537(Insulin) & ISO 7886 (TB)
Packaging	Blister Pack	Blister Pack
Sterilization	ETO	ETO
Biocompatibility	ISO 10993-1	ISO 10993-1
Labeling	21 CFR Part 801	21 CFR Part 801

G. Summary and Conclusion of Nonclinical and Clinical Tests:

The Sol-Guard Insulin and Tuberculin Safety Syringes met the appropriate requirements contained in the following standards:

1. ISO 7864:1993, Sterile Hypodermic Needles for Single Use;
2. ISO 7886:1993, Sterile Hypodermic Syringes for Single Use
3. ISO 8537:2007, Sterile, Single-Use Syringes, with or without Needle, for Insulin.
4. 11607-1,-1:2006, Packaging for terminally sterilized medical devices
5. ISO 11135:2007, Medical Apparatus – Epoxy Ethane Sterilization Confirmation and Routine Control
6. ISO 9626:1991, Stainless Steel Needle Tubing for Manufacture of Medical Devices;
7. ISO 10993-1:2006, Biological evaluation of medical devices Part 1: Evaluation and testing
8. ISO 23908:2007, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling"
9. FDA Guidance on the content of premarket notification [510(k)] submissions for hypodermic single lumen needles, April, 1993.
11. Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features. Document Issued on: August 9, 2005

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The device has been tested and found to meet all product specifications and requirements. Accelerated aging was used to verify the performance of the product over the life of the device.

Instructions for Use detail how to use the devices and the conditions of use. Product labeling clearly shows that the device is for single patient use only.

A Simulated Use Study was conducted with the Sol-Guard Safety Syringe per the requirements of the FDA's Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features.

After review of the Risk Analysis, all verification and validation test data and reports, the conclusion of the Design Review Committee was that the Sol-Guard Safety Syringe is safe and effective for its intended use and is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Sol-Millennium Medical, Incorporated
Mr. Jim Barley
Director of Regulatory Affairs and Quality Assurance
5415 Sugarloaf Parkway, Suite 2203
Lawrenceville, GA30043

Re: K132681
Trade/Device Name: Sol-Guard Insulin Safety Syringe and Tuberculin Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: April 21, 2014
Received: April 28, 2014

Dear Mr. Barley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132681

Device Name

Sol-Guard Tuberculin (TB) Safety Syringe

Indications for Use *(Describe)*

The Sol-Guard Tuberculin (TB) Safety Syringe is intended for the delivery of Tuberculin.

The Sol-Guard TB Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132681

Device Name

Sol-Guard Insulin Safety Syringe

Indications for Use *(Describe)*

The Sol-Guard Insulin Safety Syringe is intended for the delivery of U-100 insulin.

The Sol-Guard Insulin Safety Syringe Safety Sleeve covers the needle when activated. In the activated position, the Safety Shield guards against accidental needle stick.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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